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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,554	02/04/2000	James L. Winkler	03848-85586	8957

7590 11/28/2001

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/28/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/498,554

Applicant(s)

WINKLER ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-207 is/are pending in the application.
- 4a) Of the above claim(s) 117-165 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 48-116 and 166-207 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 48-147, 166-207, drawn to a method forming an array, classified in class 436, subclass 180.
 - II. Claims 148-152, drawn to an assay plate, classified in class 422, subclass 102.
 - III. Claims 153-157, drawn to a method of making, classified in class 436, subclass 183.
 - IV. Claims 158-162, drawn to a method of detection, classified in class 436, subclass 164.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each invention has separate utility such as making and analyzing arrays. See MPEP § 806.05(d).
3. Inventions IV and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in assays using labels other than dyes, such as radioactive markers.
4. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

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process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made without washing and drying.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

1. During a telephone conversation with John Iwanicki on October 1, 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 48-147, 166-207. Affirmation of this election must be made by applicant in replying to this Office action. Claims 148-165 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 48-147, 166-207 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. ('051).

8. Cozzette et al teach a method for producing an array of, e.g., polynucleotides or polypeptides (e.g., col. 18, lines 9-10 and col. 44, lines 15-16) by dispensing about 5 to 500 nl (col. 58, line 65) of solution from a syringe on a robotically controlled movement

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device (section 5.4, cols. 58-59). An array of syringes can be used (Fig. 13). A camera and reticle using a visual recognition system and artificial intelligence (col. 59, lines 7-11) are used to locate the syringe relative to the substrate. The syringe tip is positioned a defined distance from the surface to begin pipetting (col. 60). The surface on which the array is formed is treated to make hydrophobic and hydrophilic portions to contain droplets on the surface (col. 62). A cleaned silicon wafer is used as the substrate (e.g., col. 64, line 51) and a gel layer can be used (col. 66) to receive the bilayer. Linkers can be used to incorporate the biological components (col. 22, lines 10-25). Cols. 59-63 describe methods of modifying system components to provide a desired drop size and the area the drops cover, but no specific area is recited.

Cozzette fails to teach the specific size of the array or coverage of the droplets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the array with 100-1,000,000 sites in order to mass manufacture 100- 1,000,000 sensors at a time. It would have been obvious to make the droplets cover small areas in order to cover microfabricated electrical elements as disclosed. With respect to the claimed reference points, it would have been obvious to provide reference points for the visual recognition system as was known in the art. With respect to claimed methods of dispensing, it would have been obvious to use known dispensing methods for their known dispensing function. With respect to methods of detecting pipet placement, it would have been obvious to use known methods of object location for their known location/placement functions.

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9. Alternatively, claims 48-147, 166-207 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. ('051) in view of Sanz.

10. Cozzette et al teach a method for producing an array of, e.g., polynucleotides or polypeptides (e.g., col. 18, lines 9-10 and col. 44, lines 15-16) by dispensing about 5 to 500 nl (col. 58, line 65) of solution from a syringe on a robotically controlled movement device (section 5.4, cols. 58-59). An array of syringes can be used (Fig. 13). A camera and reticle using a visual recognition system and artificial intelligence (col. 59, lines 7-11) are used to locate the syringe relative to the substrate. The syringe tip is positioned a defined distance from the surface to begin pipetting (col. 60). The surface on which the array is formed is treated to make hydrophobic and hydrophilic portions to contain droplets on the surface (col. 62). A cleaned silicon wafer is used as the substrate (e.g., col. 64, line 51) and a gel layer can be used (col. 66) to receive the biolayer. Linkers can be used to incorporate the biological components (col. 22, lines 10-25).

11. Cozzette fails to teach dispensing less than 5 nl or the specific size of the array or coverage of the droplets

12. Sanz teaches a micropipet for dispensing volumes on the order of 1 nl (col. 1, line 28).

13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dispenser of Sanz in the method of Cozzette in order to dispense droplets less than 5 nl as taught by Sanz in order to use minimal reagents as taught by Cozzette. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the array with 100-1,000,000 sites in order to

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mass manufacture 100- 1,000,000 sensors at a time. It would have been obvious to make the droplets cover small areas in order to cover microfabricated electrical elements as disclosed. With respect to the claimed reference points, it would have been obvious to provide reference points for the visual recognition system as was known in the art. With respect to claimed methods of dispensing, it would have been obvious to use known dispensing methods for their known dispensing function. With respect to methods of detecting pipet placement, it would have been obvious to use known methods of object location for their known location/placement functions.

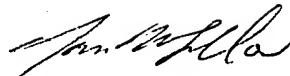
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

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Jan M. Ludlow
Primary Examiner
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jml
November 9, 2001